

Towards 'Engagement 2.0': Insights from a study of dynamic consent with biobank participants

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Digital Health
Volume 1: 1–13
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sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/2055207615605644
dhj.sagepub.com



Abstract

Web 2.0 technologies have enabled new methods of engagement, moving from static mono-directional sources of information to interactive user-led experiences. Use of Web 2.0 technologies for engagement is gaining momentum within the health sector however this is still in its infancy in biobanking research. This paper reports on findings from focus groups with biobank participants to gauge their views on a Web 2.0 dynamic consent interface. The findings from this study suggest that participants would welcome more interactive engagement with biobanks, and the opportunity to hear more about how their data and samples are being used in research. We propose that by adopting Web 2.0 tools for dynamic consent, we can move towards an 'Engagement 2.0' model whereby research participants have the opportunity for more interactive engagement with medical research, setting up a two-way communication channel between participants and researchers, for the benefit of both.

Keywords

Dynamic consent, Web 2.0, biobank, engagement, qualitative study

Submission date: 4 June 2015; Acceptance date: 15 August 2015

Introduction

The advent of the World Wide Web and the subsequent development of Web 2.0 technologies has enabled new methods of engagement.¹ Web 2.0 has been described as 'second generation of the World Wide Web that is focused on the ability for people to collaborate and share information online [...] with an emphasis on web-based communities of users, and more open sharing of information'.² This transition from a Web 1.0 approach to a more interactive, Web 2.0 user-led experience is gaining greater momentum within the health sector, particularly within clinical care where these technologies have been used to engage patients. However, adoption has been slower in medical research and in the field of biobanking, where using Web 2.0 to engage with participants is still in its infancy.

This paper reports on findings from a series of focus groups with biobank participants to gauge their views on a Web 2.0 dynamic consent interface. Dynamic consent is designed to enable biobank participants to revisit consent choices and have a more active involvement with the research of the biobank. The aims of this study were therefore to understand biobank participants'

current experience of biobanking, and to determine whether a Web 2.0 interface such as dynamic consent would be welcomed as a tool to help participants better engage with the research activities of the biobank. The paper begins by describing the way that research participation in biobanking is currently carried out, and reviews previous empirical studies to contextualise our findings. We then present the details of our empirical study with participants of three biobanks in the UK. The findings from the study suggest that the participants we studied would welcome a more interactive engagement with the biobanks. In the final section of this paper, we discuss what the features of an 'Engagement 2.0' approach might be, when applied to biobanking research.

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Biobanking participation

As biobanks are increasingly being used as a resource for medical research, they are influencing the way we view the role of research participants, the nature of their participation and the ways in which engagement might occur. Biobank governance mechanisms such as consent have been adapted from conventional models of engaging with research participants. This approach can be considered ‘Engagement 1.0’. It typically relies on paper-based information and interactions with healthcare staff. However the function of biobanks as research resources calls into question traditional forms of consent, as well as processes and practices for recruitment, participation and engagement. In clinical research, crucial elements of research recruitment typically include signing a paper consent form and obtaining information either directly from healthcare staff, or through reading leaflets or paper-based information sheets. This method of communication is enabled by regular face-to-face interactions through the clinic. However, because there are fewer clinical interactions in biobanking, there are fewer possibilities to engage with participants, with participation and engagement practices largely concentrated at the start of the process, at the point of recruitment and sample collection as the only face-to-face interactions.

Biobank research therefore involves a more abstract understanding of participation. Here, the participant is approached during their clinical care, or responds to an advert for healthy participants, agrees to enrol with the biobank, signs a consent form and provides samples and data. These are stored in the biobank for future research use, and unless further samples or data are required at a later date, this signifies the end of the participant’s active involvement with the biobank and the associated research studies. As participants often give a broad consent to allow for use of samples in unspecified future research,³ there is no need to go back to them for a new consent when a new study using the biobank collection commences. The role of biobank participants therefore becomes a passive one after the initial enrolment and sample collection. Nevertheless participants’ samples and data are still involved in research as they may be accessed, tested and used in projects for many years after the initial enrolment.

One dilemma for biobanks is the extent to which their activities can be considered transparent in the absence of ongoing participation and engagement with biobank participants. Relying on a broad consent heightens this dilemma. For example, the controversy that surrounded the Icelandic population biobank in 2000 has demonstrated the importance of public trust.⁴ To improve transparency and help develop accountability, and thus demonstrate trustworthiness,

some biobanks have developed innovative ways to inform and involve participants beyond the initial face-to-face recruitment.^{5,6} While such initiatives are important, any mono-directional information flows (newsletters, websites) follow a ‘1.0’ approach. Other forms of engagement may also be limited to participant representatives rather than the whole cohort. Web 2.0 engagement for biobanks would need to move towards more interactive dialogues that potentially could enable participants to interact with the research team, to provide new consents when required as well as being able to receive regular updates on the research conducted on the biobank. This should not simply be viewed as an update in the use of technology, but as an overhaul of the philosophy behind participation and the role of participants in biobanking research, contributing to the growing belief that participants are research partners, not passive subjects. The potential to address the concerns about broad consent, the passive nature of biobank participation and concerns about maintaining public trust were the impetus for the Web 2.0 dynamic consent study.

Empirical studies in biobanking

Several empirical studies have sought to establish the views of research participants on various aspects of these challenges faced by biobanks. There is a considerable body of empirical work on engaging patients and publics in biobanking research.^{7,8} This includes studies designed to gauge the attitudes of various publics to biobanking projects,^{9–11} and research on the views and motivations of actual and potential biobank participants.^{12–16} Studies have also addressed key concerns such as broad consent, trust, reciprocity and the use of Web 2.0 technology.

A number of recent large-scale studies investigating prospective consent preferences (e.g. broad versus traditional informed consent) among non-patient adults in Scotland,¹⁷ and the US reported a preference amongst respondents for a single, one-off, consent at the time of donation (effectively a broad consent since future uses cannot be foreseen).^{18,19} In a meta-analysis of the quantitative and qualitative sociological literature on public and patient attitudes to biobanking Lipworth et al. reached a similar conclusion;⁷ that ‘few people demanded recurrent, project-specific consent and few wished to place limits on the uses to which their tissue could be put’.

Care must be taken, however, when evaluating these results. For several studies, while a statistically significant preference for one form of consent over another can be detected this is not necessarily indicative of a clear majority preference.¹⁷ In the case of prospective ‘public attitude’ surveys on biobanking, of which the

existing literature contains a prevalence,⁷ Johnsson et al. found that reported willingness to share data and tissue for research was prone to both overestimating and underestimating recorded participation levels in different cases which limits its predictive power.²⁰

Many of these studies focus on the initial engagement with biobanks, including investigating the conditions under which biobanks and participation in biobanking studies can secure social legitimacy.²¹ This is often expressed in terms of ‘public trust’. Although a detailed review of the different conceptions of ‘trust’ mobilised in different studies is beyond the scope of this paper, trust is widely regarded as a critical factor in ensuring the viability of biomedical research,²² and has been found to vary in relation to levels of public trust in national governments, types of institutions involved in biobanking,^{7,10,23} different social and professional groups and a range of individual and group characteristics including whether people are healthy volunteers or patient donors.^{7,8,15,16} A related strand of scholarly inquiry also examines different governance models for emerging biobanks as a way to test the ‘public appeal’ of different options,¹⁷ and as sites for community engagement through deliberative democracy approaches.^{5,24,25}

Recent studies have identified key elements that can facilitate trustworthiness. Participants are more trusting if they are recruited by a healthcare professional and there is ongoing engagement.^{26,27} Effective engagement therefore needs to be substantive, valued by all parties and involve an ongoing relationship.²⁸

Watanabe et al. identify ongoing communication as an important part of an engagement strategy and for sustaining trust between participants and biobanks.²⁹ Some biobanks, such as UK Biobank and the Norwegian Mother Child Cohort Study provide regular updates to participants, but it is unclear how widespread such communication practices are and what form they take (mono or bi-directional), how valued they are by participants and which approaches are particularly effective. Known examples are largely Web 1.0, and it is thus recognised that:

[T]he vast repertoire of Web 2.0, from YouTube to social media, still remains to be integrated and used by many biobanks, whose communications efforts are all too often limited to rather self-contained web pages that are sorely lacking in interactive features that could engage people.¹¹

Recent studies into the attitudes of biobank participants have addressed the issue of reciprocity as another feature of the engagement process. Nobile et al. argue that two kinds of reciprocity can be identified in participant accounts of reasons for participation in

biobank studies: ‘altruistic reciprocity’ where participants reported a desire to ‘give something back’ in return for past medical care and a more ‘self-interested’ reciprocity where participants also expect to receive something of benefit to them in return for giving their samples and data to a biobank.¹⁶ The latter form of reciprocity is similar to the idea that for many participants, sharing samples and data with a biobank is a ‘conditional gift’, which is freely given but with an expectation of particular behaviours and actions by the recipient, identified by Hobbs et al.¹⁴

The link between reciprocity and engagement becomes clearer when some examples of reciprocity from biobanks that participants have requested/received include feedback of information on how their samples have been used in research, feedback of general research findings, agreement that findings will be made available to the wider scientific community, agreement that research results, samples, data, etc. will remain in the public sphere and not be privatised, and the return of personal health information.^{9,13,14,16}

The dynamic consent study

The concept of dynamic consent (DC) grew out of the EnCoRe project (2008–2012), which aimed to investigate the viability of electronically-mediated flexible management of consent and personal data across a range of settings, including biobanking.³⁰ In the biobank context, the DC interface connects participants to the biobank(s) to which they have donated material and data. It is intended to make biobanking more participant-centred by making it more dynamic and more interactive.³¹ The DC interface can act as a mechanism for obtaining consent for new research carried out on the biobank; providing more information about biobanking and research in a range of accessible formats as well as feeding information back to participants, from a ‘thank you’ message upon donation, to outcomes of particular studies and potentially even health-related findings.³² It allows participants to set (and alter) their preferences, both in terms of consent and the level, frequency and type of communication they wish to receive from the biobank studies in which they are involved. Importantly, a DC system does not mandate ongoing involvement. Participants can choose, for example, to give, effectively, a broad consent with little further contact if that is their preference, but unlike paper-based consent systems they retain the option to revise this choice at a later date. This approach is increasingly being tested in research projects.³³

Study design

The purpose of this empirical study was to determine (1) biobank participants’ current experience of

biobanking, and (2) whether a Web 2.0 DC interface would be welcomed as a tool to engage with the biobank. Donating blood and/or tissue samples to biobank research is not yet a commonplace occurrence. The ‘general lay public’ was not therefore considered a suitable audience to evaluate and give feedback on the usefulness, relevance and accessibility of DC. The study design sought to obtain feedback from individuals for whom donation was a relatable experience, including biobank donors with different medical conditions as well as healthy volunteers to incorporate a range of experiences and motivations for donation.^{7,34}

Recruitment

The recruitment and all subsequent empirical work were carried out between January and May 2013. Participants were recruited from three biobanks (see Table 1 for details). Each biobank had a different research focus. Participants recruited from Biobanks 1 and 3 were, or had been patients with musculoskeletal disorders and sarcoma respectively. Biobank 2 provided participants from a cohort of healthy volunteers. This approach had the benefit of providing a list of prospective participants in the form of known tissue donors across a range of conditions and with reliable contact details. In addition all three banks were governed by the same NHS Hospital Trust. Research Ethics Committee (REC) approval from the NRES Committee West Midlands – South Birmingham to carry out interviews in the jurisdiction of this Trust had already been obtained as part of the EnCoRe project (see Whitley et al. for details),³⁵ and permission was successfully sought to extend this approval to cover additional focus groups.

Participants from each biobank were recruited by letters, accompanied by a participant information sheet (PIS) inviting them to discuss their experiences and give feedback on the DC interface. An additional leaflet provided information about DC. As the details of each biobank’s donor list are confidential, the

invitation letter and PIS were prepared by the research team, and sent by the biobank staff. Biobanks 1 and 2 had previous experience of sending out surveys and questionnaires to their donor populations and, based on this, predicted an expected response rate of 10%. Each group sent out 300 invitation packs with the intention of recruiting 30 participants from each biobank.

With Biobank 3, the particularly fraught, ongoing nature of sarcoma treatment meant that additional concerns needed to be met in participant recruitment. Letters were targeted exclusively to individuals who the lead clinical research nurse deemed to be at an appropriate stage in their treatment where their participation would not cause undue physical or emotional stress. Fifty carefully targeted letters were sent to potential participants from Biobank 3. In addition, the lead clinicians involved requested that the clinical research nurse be present during all interactions with patients to respond to any medical questions the participants might have. Response rates were relatively low for all three biobanks (ranging from 3–12% across the groups) (see Table 2 for details).

Focus groups

Focus groups were the preferred method of data collection. Focus groups can be understood as organised discussions that emphasise communication *between* research participants in order to generate data based on group interaction.^{36,37} As a consequence they are particularly useful for revealing different perspectives, beliefs and attitudes, for example when one person’s contribution triggers responses from other participants.^{36,38} Despite the low levels of response, it was possible to organise participants from Biobank 1 into three focus group sessions with a further two sessions for participants from Biobank 2. For Biobank 3 it did not prove possible to agree a date and time when all respondents were available. It was considered undesirable to mix individuals from Biobank 3 into other focus

Table 1. Characteristics of biobanks involved.

Biobank	History	Disease focus	Type of participants recruited	Tissue type
1	Established	Musculo-skeletal diseases	Adults with current or prior musculo-skeletal disease	Tissue samples removed during surgery to repair or replace damaged hip, knee, ligament or tendon
2	Established	Diabetes	Adult healthy volunteers	Healthy tissue samples for use as controls
3	Recently converted from tissue collection to a biobank	Cancer	Adults with a specific cancer sub-type	Tumour tissue removed during surgery

Table 2. Recruitment and focus group characteristics. Response rates listed here are based on the number of individuals we were able to recruit within the allocated time and whom we were able to assign to a pre-arranged focus group session.

Biobank	Recruitment		Response		Focus groups		
	Letters sent	Targeting?	Number recruited	Response rate	Number of groups	Size (persons) per group	Family members included?
1	300	Previous survey responders	17	5.7%	3	6; 8; 3 (participants P1–P17)	Yes
2	300	No	9	3%	2	4; 5 (participants P18–P26)	No
3	50	Patients at appropriate treatment stage only	6	12%	2 × interviews 1 × focus group	Interview 1: 2 people; Interview 2: 1 person; Focus group: 3 people (participants P27–P32)	Yes

groups as their particular experiences would possibly be lost in the group discussion. Instead it was preferable to hold one small focus group with three Biobank 3 participants and conduct two additional interviews with the other one and two (related) respondents respectively. Although focus groups were the preferred method because of their particular advantages, we decided it was better, and more ethically appropriate, to allow patients who wanted to contribute to do so even if enabling their contribution meant using a different method of data collection. To maximise the comparability of data across focus groups and interviews the same set of prompting questions and the same procedures were employed for both focus groups and interviews. For the purposes of data analysis and interpretation the information from the two interviews was treated as a set of additional contributions to the single Biobank 3 focus group.

To facilitate the focus groups a three-person research team was present; one member to act as a mediator, a second to act as a note-taker and the remaining person to monitor the recording device. The focus group discussion was divided into two parts. In the first part, the aim was to clarify how participants understood their existing relationship with their biobank. The mediator asked each group a set of introductory questions about participants' experiences of giving consent and background information. This encouraged interaction among group members, with the mediator responsible for standardising the questions for each group, and including less responsive members and limiting dominant speakers while trying to allow group dialogue to flow.^{36,39}

In the second part, participants were presented with a functioning mock-up of the DC interface implemented on a tablet computer. The interface contained

a range of information types and options that could be accessed and altered through a touch screen mechanism. These data and preferences were not integrated to the information management system of any actual biobank but allowed participants to explore and play with the features without concern about real-time consequences. When it came to introducing the tablet, participants were arranged into small groups of 2–3 persons each being given a tablet computer to interact with. All members of the research team present participated in this activity. They helped ensure that all focus group participants spent time using the tablet. The researcher could respond to questions and, occasionally, prompt the participants to explore further aspects of the interface. This section lasted approximately 20 minutes, after which the whole group reconvened to discuss their perceptions of the DC interface.

The participants' use of the DC interface was intended to elicit two forms of responses. The first, not reported here, related to the specific instantiation of the interface providing feedback to the system developers for how they might improve the usability of the interface (e.g. by changing wording on the screens). Second, by giving the study participants access to a 'working' implementation of DC, we sought to elicit responses and reactions to the range of options for communication and interaction beyond their previous experiences of paper forms and broad consent. The focus group method enabled individuals to discuss their responses to the interface with each other, discussing the relevance of each feature but not necessarily reaching consensus on which aspects were most or least useful. Although not an explicit research aim, allowing study participants to explore the DC interface also resulted in them talking extensively about their biobanking experience more generally.

Data analysis

An audio recording was made of each focus group and interview, with the explicit consent of all participants. The recordings were transcribed by a professional transcription service. These transcripts were independently coded and then compared. The initial coding was used to produce broad thematic codes based on issues identified from the literature. The individually coded transcripts were compared and the coding frames discussed until a consensus framework was developed. Examples of thematic codes included 'Recruitment' to capture discussions of participants' experiences of being asked to take part in the biobank, 'Consent' which was intended to record attitudes and pronouncements on the value of consent, or 'digital divide' for statements relating to suggestions that different age groups might respond differently to digital technologies (especially the DC interface). These are analyst's categories rather than participants' categories. This coding framework was then applied to the remainder of the transcripts using manual coding and a final review of all coded transcripts for consistency was undertaken.

Findings

Opinions on consent and withdrawal

The study elicited participants' views about existing types of consent, especially broad consent, and learned about their experiences as biobank donors. Across the different groups, participants presented a generally positive view of the (broad) consents they had given for the use of their samples and data and no participant reported a current or anticipated desire to withdraw from any of the biobanks they were involved with. For some participants, consent was framed as an agreement or contract that should not need revisiting; 'once I've given my consent then I've given my consent' (Biobank 3, P29), and where donors had a responsibility to uphold their agreement: 'I personally wouldn't sign up to do it if I thought I would need to withdraw at any stage' (Biobank 2, P19).

Others took a different approach, regarding the decision to give consent as being safeguarded by the option to withdraw from the biobank if necessary: 'if you did want to opt out at any point, you had that power to do so' (Biobank 3, P29). One group member described the option of withdrawal as conferring a 'feeling of confidence that you can, at any point, say "Actually, no"' (Biobank 2, P20). Additionally, a few focus group participants demonstrated a significant lack of understanding of the implications of broad consent, claiming that

'... it's not like I've just given consent for anything' (Biobank 2, P20) and 'you can't be expected to consent to every future study that's going to come along' (Biobank 2, P22). However, in terms of their satisfaction with one-off broad consent for biobanking the findings from these focus groups are largely in line with the findings of previous studies.^{7,17,18}

Experiences of giving consent

Participants were asked to reflect on how they came to donate tissue to a biobank. Where appropriate, prompts were used to introduce specific discussion around giving consent. Some group members reported favourable experiences of giving consent:

It was very positive, [...] you had it in advance and then when you turned up, they went through it and made sure that you understood everything (Biobank 2, P21).

Whilst for others it was not a wholly negative experience, it was something 'rather perfunctory' (Biobank 3, P29), simply 'a piece of the bureaucracy that you have to go through' (Biobank 1, P3) and not an event that was felt to create an ongoing relationship between participant and biobank:

I remember a blue flimsy paper that I remember signing, and I remember being told that my hip joint would be taken [...] And like you I haven't thought a thing about it since (Biobank 1, P3).

One potential reason for this observation is the timing of consent. This was particularly evident in groups where participants had tissue excised as part of their treatment and where consent giving was closely linked to medical procedures. Receiving a diagnosis and being told that surgery was required was described as 'very stressful' and 'emotional' (Biobank 3, 28) and respondents spoke of being 'in a state of shock' (Biobank 3, P29) following the news. Donating excised tissue to the biobank was portrayed very much as a secondary concern at the time.

The reality of obtaining consent for research using a paper-based system is that it must be done when patients are in clinic as there is little opportunity to contact people otherwise. Recruiting patients into research during a visit to the clinic means that clinical needs often eclipse research as a priority. For the patients concerned this can be a stressful time and may explain why some participants struggled to remember the details of consent or recall a clear motivation for giving consent.

Motivations and concerns

The motivations reported by study participants and across groups for taking part in research include some form of association with an existing group affected by a disease or condition as well as reciprocity in both categories identified by Nobile et al.¹⁶ Examples of ‘altruistic’ reciprocity as motivation include identification of research as ‘a very important part of medicine’ (Biobank 3, P29), to ‘benefit future generations’ (Biobank 2, P22), and a desire to ‘give a little bit back’ (Biobank 1, P32), and to add to ‘the greater good’ (Biobank 2, P23).

These motivations appear to be clearly linked with a conception of biomedical research as clear ‘good’ – a positive force for progress and the alleviation of suffering. This understanding is reflected in the reported satisfaction with broad consent and in the difficulties participants experienced when trying to conceive of a circumstance in which someone would want to exercise the option to withdraw from a biobank: ‘if it’s all for research and promote health and the correct medicines, I can’t see any reason why you would want to pull out’ (Biobank 2, P23). This was supported by another focus group participant who opined:

So, anything I can give them [...] is for my benefit as much as for my children’s, or my grandchildren’s benefit. So, I think it would very naïve if they withdrew, personally (Biobank 1, P14).

Although, for the reasons outlined above, none of the participants anticipated withdrawing from the biobank, being asked for consent and offered the option of withdrawal were largely seen as options that were ‘polite’ or reassuring. Not giving consent, or withdrawing it at a later date were largely presented as something that might be required only by ‘others’ such as people with unspecified ‘religious or cultural’ motivations.

One participant identified a different function of being offered the option of withdrawal – as a (symbolic) means of demonstrating respect for donors as people: ‘I can’t see it being used, but I think it, I think you have to put it in to make people feel that they are being helpful rather than just simply tools being used’ (Biobank 1, P17).

As noted above, a key benefit of the focus group approach is the evolving discussion between participants. In the course of the group discussions specific concerns about future uses of samples or data emerged that were often offset by expressions of the trustworthiness of institutions and the desirability of research. The most commonly cited trusted institutions were the

National Health Service and local universities. Medical expertise, for example ‘high level doctors’ (Biobank 3, P29), was also reported as a source of trust, while ‘industry’ and insurance companies were raised as types of organisations inspiring suspicion. This is similar to phenomena identified by Hobbs in previous studies of UK and German biobanks,¹⁴ where potential dis-benefits to biobank participants such as privacy risks were balanced by the perceived benefits for wider communities such as particular patient populations or even the ‘general good’.

Some common concerns were raised about the security of personal medical data, the possibility of findings (especially from genetic research) that the respondents would not want to know, and recognition that ‘there is potentially a risk that your samples or your data could be used for something perhaps you’re not happy [about]’ (Biobank 2, P21).

While we did not explicitly ask participants about their motivation for attending the focus groups, several suggested that they were similar to their reasons for taking part in biobank research, specifically that:

I’m giving back a little bit perhaps to the NHS for all the stuff I’ve had out of it. (Biobank 1, P5).

and that it would be an ‘interesting afternoon’ and ‘something different to do’ (Biobank 1, P5). It was also apparent that for a number of participants, the focus group invitation letter was their first reminder that they had signed up to take part in the biobank, as they ‘haven’t thought any more about it until I received your letters’ (Biobank 1, P2).

Participants didn’t appear to have specific impressions about dynamic consent before joining the focus group, which provided an opportunity to find out more about an area they had previously ‘not really thought about’ (Biobank 3, P29). As one participant described:

I’m perfectly happy to be here and talk but I’m still, to a degree, in the dark as to what I’m doing here. Now, I don’t mind being here, but I don’t quite know what I’m helping you with (Biobank 1, P17).

But several suggested they thought it was a relevant topic in general:

When I got your letter it was quite interesting to see that this was, you know, quite a serious area of research and that you were, you know, clearly thinking about patient involvement on a level that I’d not really thought about (Biobank 3, P29).

Responses to the dynamic consent interface

The DC interface that study participants used included the option to ‘log in’ to a personal account and not only revisit individual consent choices, but also to access information on sample projects that they had ‘consented to’, including descriptions of the project aims, the institutions involved, project duration and broader context of the disease conditions involved. It also described how the research might help in treatment or prevention and how this could allow for tailored participant engagement depending on the needs and capabilities of the research programme.

This function of the DC interface prompted considerable discussion across groups. For a number of participants, this property of the system was regarded as a potential improvement on their current experiences of having given consent to a biobank. This option was regarded as helpful both for addressing the timing of consent:

So that you are going into these [situations of being asked for consent] completely with your eyes open, and perhaps not under the stress of [...] a big meeting when you’re discussing the actual surgery and so on (Biobank 3, P29),

and for helping others who had little recollection of what they had agreed to, or had ‘absolutely no idea what research is being done on whatever was sent off to the biobank’ (Biobank 3, P29). The DC interface does not remove the requirement for initial face-to-face consent, but it does allow details to be revisited and checked at a later date: ‘if we can log on online back to our person[al] information we can double-check that we ticked that box to say “Yes”’ (Biobank 2, P24).

Although many participants were unaware of what biobanking research entails in practice, this did not appear to be the result of a lack of interest. Many participants agreed that they would be interested to know how research was progressing, and indeed that as a donor: ‘[y]ou should know what’s going on’ (Biobank 1, P3). A participation information sheet offers little opportunity to provide detailed information in answer to these broader questions, not least because it is often produced and approved at an early stage of research when few results are available. Although some biobanks provide updates and newsletters to inform patients of how research is progressing this often provides generic, rather than personalised information. Focus group participants in this study welcomed an opportunity for more specific information ‘about what the actual research was and what the end result of the research is meant to be’

(Biobank 1, P6) and ultimately to know whether their contribution ‘helped to answer a question’ (Biobank 2, P22).

The contribution research makes to medical progress, was cited as a motivation of biobank participants, as one participant expressed:

I think we all have a belief in research, because without research and experimentation you don’t get any further forward (Biobank 1, P11).

It is perhaps not surprising that many would like to have more information on the outcomes of research, and their specific role in this progress:

It would be interesting to know if they scored a hit with your...you know, something you’d contributed had helped take something a bit further forward (Biobank 1, P3).

This can be considered an additional form of more personal reciprocity between biobanks and participants,¹⁴ and supports the contention that donor endorsement of broad consent does not necessarily constitute a rejection of ongoing interest in how their samples and data are used.¹⁰

Benefits of tailored information

Focus group participants also recognised that, within groups, different people were approaching participation from very different viewpoints, and that they ‘all have [their] own interests and [their] own scope of knowledge’ (Biobank 1, P15). Accordingly it was recognised that the levels and type of information accessible through a DC interface would be best tailored to individual needs, as different users ‘could access it at different levels, depending on where they’re coming from’ (Biobank 3, P29).

The digital nature of the DC interface also allows for the deployment of a variety of media to provide information in different ways. This was recognised as an advantage by some participants:

There’s a place for [videos] and... a place for the written word and some suit some people, and some will suit the others (Biobank 1, P17).

The DC interface, by presenting a personalised profile that would allow participants to select the sort of information they wished to receive alongside updates on their data and samples would go a long way towards satisfying participants’ desire to be better informed and would play an important role in making biobank consent more meaningfully informed.

Promoting research participation

Another feature of the DC interface was the inclusion of information about other biobank research studies that the participants might wish to participate in. Several focus group participants welcomed enhanced communication and information about such opportunities to put themselves forward for other research projects:

I think it's a way of, you know, encouraging, you know, participation in trials (Biobank 3, P30).

By promoting ongoing engagement beyond the initial consent procedure by 'being able to tick a box to sign up for something' and 'being able to access other biobank studies' (Biobank 2, P24), donor engagement with the biobank can be transformed into an ongoing partnership for engaging in future research.

If it was a little box I can tick to say "Yes, I'm happy for you to pass on my biobank information to [specific] research project[s] because I'd be interested in getting involved" that's great (Biobank 2, P26).

Given that the costs of re-contact are often cited as one of the major challenges for biobanking research,³ there are clear benefits offered by the DC interface that allows patients to drive their own participation, rather than placing the onus on the research team to drum up support.³²

Towards Engagement 2.0

Whilst the DC approach relating to providing, reviewing and changing consent preferences, was largely welcomed by study participants, we were particularly struck by the interest that was sparked by the possibility to use the interface to transform engagement, which is a significantly different function of the DC interface than the granular consent choices. The opportunities for more dynamic approaches to giving and revoking consent thus became the vehicle for introducing more diverse approaches to engaging with biobanks, approaches that echo the characteristics and motivations for Web 2.0.

The central benefits that were highlighted as important to the biobank participants involved in these focus groups were:

- the opportunity to improve on the timing of consent, and enable participants to reflect and review consent decisions over time including having a record of previous consent decisions available electronically;

- the opportunity to hear about the research their data and samples have contributed to, and to receive updates on further projects;
- the ability to have greater control over their involvement and to feed more directly into the research process through interactive engagement;
- and the chance to receive tailored information, in a variety of media, to suit the interests and understanding of the individual.

We suggest that these five characteristics, namely timing, research participation, autonomy, consent and knowledge (TRACKs), form the central tenets of an 'Engagement 2.0' approach, and characterise what is meant by DC, not just as a new technical solution, but a system-wide behaviour change. Additional characteristics are likely to arise as further experience with Engagement 2.0 occurs and participants request further interactivity options from the biobanks they are working with.

This provides a more nuanced solution to enable reciprocity to work in practice and to suggest some ideas of the kind and formats of information that people would like provided. It moves away from polarised arguments about broad vs repeat consent and about how much information should be included on participant information sheets to make consent adequately informed, by allowing participants to make these decisions for themselves, about how engaged they wish to be, and which information they need to access to decide whether or not to take part.

Table 3 outlines the key features (TRACKs) of Engagement 2.0, indicating how they differ from more conventional (Web 1.0) approaches. Each feature is illustrated with data from the study.

Study limitations

This was a local preliminary study of the DC interface with a small sample size. The response rates to the recruitment efforts were low so that everyone who volunteered to take part in the study was accepted. There was no opportunity to select participants to ensure a representative sample on the grounds of age, gender or other criteria. There were no participants from BME groups. The main limitation of this study is that as volunteers the participants likely represent a self-selecting group who were already motivated to take part in research in general and are therefore also more likely than other biobank donors or the general public to be in favour of learning more about biobanking and being engaged through ongoing communication with a biobank. It is also possible that the participants' attitudes to research and to the DC interface were affected by a desire to appear morally virtuous to members of the research team and to each other. However, they were

Table 3. The TRACKs of Engagement 2.0.

Feature	Engagement 1.0	Engagement 2.0	Engagement 2.0 examples from the study
Timing	Linear flow, one time decisions	Iterative processes supported, ability to review and revise decisions	<p>'I didn't realise that I was involved, but I remember when I had the op you took a whole lot of extra blood samples' (Biobank 1, P1)</p> <p>'I was asked to take part in a study, it was not going to hurt or cost, so I thought 'why not', it wasn't a deep, deeply-thought decision, it was just 'Yeah, all right, why not', you know, if something helps, I'm quite happy to do that, I didn't consider for one moment the long-term benefits if you like, I was just happy to take part and it's just sort of carried on' (Biobank 2, P23)</p>
Research participation	Flyers and leaflets Conversation from consultant to participant	Option to search for participation opportunities Dialogue with researchers Notification of opportunities	<p>'Yes, it is something I've mentioned before, I would like to more of what you are doing, but I would like to know in fairly lay terms' (Biobank 1, P17)</p> <p>'The more people you get, the more people you'll get, people will talk to people' (Biobank 2, P20)</p>
Autonomy	Passive	Active, empowered, ongoing	<p>'It makes it more sort of dynamic, and interactive isn't it the current system where we sit and wait to hear something' (Biobank 2, P25)</p> <p>'It's, you know, looking up things about myself and my cancer and so on, I've not wanted to do, but possibly looking at what has happened to what I've donated is less pertinent to actually my actual cancer and therefore might be much more interesting to read' (Biobank 3, P29)</p>
Consent	Paper based, broad	Dynamic	<p>'At the moment, we're, you know, we're giving our consents and then go away and we don't think any more about it' (Biobank 1, P5)</p> <p>'I think it was this point in my consent choices that was the only thing that had occurred to me in advance, when I got this was to include in here some way of differentiating between sort of academic research and more commercial research' (Biobank 3, P30)</p>
Knowledge	Biobank specific leaflets and resources	Participant specific information, opportunities to share experiences and questions with community of participants	<p>'I suppose you'd you want an email alert to say "Just used your sample" and then you can log in and see what it's being used for. . .' (Biobank 2, P21)</p> <p>'At the time I wasn't really concerned as to who was getting access to it and what they were doing, but I suppose in the light of your research, it might be quite nice to know if there's an end result. But monitoring what's happening along the way, you know, I hadn't really, you know, thought of' (Biobank 3, P29)</p>

not deterred from discussing other potentially problematic behaviours, such as admitting that they could not remember the details of giving consent to donate their tissue to the biobank.

Conclusions

The aims of this study were to understand the views of biobank participants about their experience of being

involved in a biobank, and elicit how they reacted to the opportunities that the DC approach offered and whether it would increase their confidence and trust in their involvement with biobanks. Participants were shown a demonstration of the DC system that offers a more dynamic, Web 2.0 interface for managing their consent preferences as well as offering access to biobank related sources, which we are calling an Engagement 2.0 approach.

Biobank participants in our study are supportive of biobank research, and were reasonably happy with the method for being consented into the biobank – given that they had all agreed to be recruited into the biobank, and then to take part in our focus groups, this was not an unexpected finding. It demonstrated the considerable trust they had in the clinical staff that were treating them, which in turn had encouraged them to become involved in research. There was also evidence that this group were altruistic and supportive of research which they saw as a way of helping their families and subsequent generations.

For this group, it was not an issue to be asked for a broad consent to have samples deposited into a biobank for many different research purposes by the clinical staff that they trusted. However, they considered that obtaining consent was a mandatory requirement, and individuals should always be asked to be involved in research and to be recruited into a biobank. When presented with the possibility of being able to change their consent preferences through the DC interface, they could imagine that others might find the consent choices useful – at the very least being able to have a choice was seen as a courtesy, and demonstrated a more involved role in the research project. It was also essential to have the ability to withdraw at any time even though they felt they personally would never have the need to exercise this option, although some had not fully appreciated what they had consented to given the close timings between surgery and participation in the biobank.

When presented with the Web 2.0 functionality that DC enabled, biobank participants were enthusiastic about the potential to know more about the research process and how their samples were being used. They could understand the benefits of being able to get more information if they needed it, rather than only having a paper information sheet. They responded positively to being able to check what they have agreed to, after being recruited in a busy clinical setting and also to specifying how and when they received information. This was regarded as a way to acknowledge the contribution that they had made to research by donating their samples, but also to know about ways to become enrolled in other research activities. They regarded these possibilities as offering more in terms of information than they have received when they had been enrolled in the biobank.

This study has firstly demonstrated that research participants we studied would welcome more information through an online interface. However, perhaps more importantly, their suggestions for how the DC interface could be developed show an appetite for greater interaction which can be seen as the beginnings of what we have described as Engagement 2.0. This study provides the foundation for other studies

exploring the use of Web 2.0 technologies in engagement, but also has provided the basis for development of the DC interface in biobanking.

The next stage will be to fully test the DC interface within a research study to explore the downstream implications of both the consent and engagement functions, and the realities of the model in practice. Existing biobank resource constraints (financial, technological, staffing) may limit the kinds of Engagement 2.0 facilities offered to participants. For example, study design considerations may limit the range of consent revocation options available to participants and, unless explicitly costed, there might only be limited staff time that could be used to discuss research participation options with researchers. Similarly, there may need to be a culture change for this new technology and approach to engagement to be fully adopted and integrated into practice to ensure that participant specific information and opportunities to share experiences as an online community of equals are built and maintained. How this fits with current research practices, and where there are improvements and efficiencies that can be made through the use of DC will need to be fully explored within a research setting.

Funding: Background work was partially supported by the Technology Strategy Board, the Engineering and Physical Sciences Research Council and the Economic and Social Research Council (grant number EP/G002541/1) for JK and EW. This represents independent research partly funded by the National Institute for Health Research (NIHR) sarcoma theme of the Musculoskeletal Biomedical Research Unit of the Oxford University NHS Trust based at the Botnar Research Institute at the Nuffield Orthopaedic Centre. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

HT is funded under the Innovative Medicines Initiative joint Undertaking under grant agreement no. 115005, resources of which are composed of financial contribution from the European Union's seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution, and by Horizon 2020 (H2020/2014-2020) under project ID 643439. MM is funded through Innovative Medicines Initiative Joint Undertaking under Grant Agreement number 115439 (StemBANCC), resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution. JK is funded under Wellcome Trust Award 096599/2/11/Z and the EU F7 project BIOSHARE.

Conflict of interest: None declared.

Guarantor: HT.

Ethical approval: The ethics committee West Midlands – South Birmingham approved this study (Rec number: 10/H1207/37).

Contributorship: HT, MM and JK were involved in coordinating and facilitating the focus groups. HT, MM and EW coded and analysed the focus group transcriptions. All authors reviewed and edited the manuscript and approved the final version.

Peer-review: This manuscript was reviewed by Graeme Laurie, University of Edinburgh and one other reviewer who wishes to remain anonymous.

Acknowledgements

We would like to extend our gratitude to the biobank managers and research teams that supported us in the recruitment processes for this study. Our thanks also go to Patrizia Bertini for help with transcript coding during the early stages of analysis, and to David Lund (HW Communications Ltd) for help with the Dynamic Consent interface prototype.

References

- O'Reilly T. What is Web 2.0? Design patterns and business models for the next generation of software, www.oreilly.com/pub/a/web2/archive/what-is-web-20.html?page=1 (2005, accessed 30 April 2015).
- Beal V. 'Web 2.0' Webopedia, www.webopedia.com/TERM/W/Web_2_point_0.html (accessed 30 April 2015).
- Petrini C. "Broad" consent, exceptions to consent and the question of using biological samples for research purposes different from the initial collection purpose. *Social Sci Med* 2010; 70: 217–220.
- Winickoff D. A bold experiment: Iceland's genomic venture. In: Mascalzoni D (ed.) *Ethics, law and governance of biobanking: national, European and international approaches*. Dordrecht: Springer, 2015, pp. 187–209.
- O'Doherty KC, Hawkins AK and Burgess MM. Involving citizens in the ethics of biobank research: Informing institutional policy through structured public deliberation. *Social Sci Med* 2012; 75: 1604–1611.
- Lemke AA, Wu JT, Waudby C, et al. Community engagement in biobanking: experiences from the eMERGE network. *Genomics Soc Policy* 2010; 6(3): 50–67.
- Lipworth W, Forsyth R and Kerridge I. Tissue donation to biobanks: a review of sociological studies. *Social Health Illness* 2011; 33: 792–811.
- Gaskell G, Gottweis H, Starkbaum J, et al. Publics and biobanks: pan-European diversity and the challenge of responsible innovation. *Eur J Hum Genet* 2013; 21: 14–20.
- Godard B, Marshall J and Laberge C. Community engagement in genetic research: results of the first public consultation for the Quebec CARTaGENE project. *Community Genet* 2007; 10: 147–158.
- Tupasela A, Sihvo S, Snell K, et al. Attitudes towards biomedical use of tissue sample collections, consent, and biobanks among Finns. *Scand J Public Health* 2010; 38: 46–52.
- Gottweis HGG and Starkbaum J. Connecting the public with biobank research: reciprocity matters. *Nat Rev Genet* 2011; 12: 738–739.
- Hoeyer K. The power of ethics: a case study from Sweden on the social life of moral concerns in policy processes. *Social Health Illness* 2006; 28: 785–801.
- Vermeulen E, Schmidt MK, Cornel MC, et al. Connective tissue: Cancer patients' attitudes towards medical research using excised (tumour) tissue. *Biosocieties* 2011; 6: 466–486.
- Hobbs A, Starkbaum J, Gottweis U, et al. The privacy–reciprocity connection in biobanking: comparing German with UK strategies. *Public Health Genomics* 2012; 15: 272–284.
- Pellegrini ICC, Mancini J, Viret F, et al. Contributing to research via biobanks: what it means to cancer patients. *Health Expectations* 2014; 17: 523–533.
- Nobile H, Vermeulen E, Thys K, Bergmann MM and Borry P. Why do participants enroll in population biobank studies? A systematic literature review. *Expert Rev Mol Diagn* 2013; 13: 35–47.
- Haddow G, Cunningham-Burley S and Murray L. Can the governance of a population genetic data bank effect recruitment? Evidence from the public consultation of Generation Scotland. *Public Understanding Sci* 2011; 20: 117–129.
- Simon CM, L'Heureux J, Murray JC, et al. Active choice but not too active: Public perspectives on biobank consent models. *Genet Med* 2011; 13: 821–831.
- Platt J, Bollinger J, Dvoskin R, et al. Public preferences regarding informed consent models for participation in population-based genomic research. *Genet Med* 2014; 16: 11–18.
- Johnsson L, Helgesson G, Rafnar T, et al. Hypothetical and factual willingness to participate in biobank research. *Eur J Hum Genet* 2010; 18: 1261–1264.
- Carter P, Laurie GT and Dixon-Woods M. The social licence for research: why *care.data* ran into trouble. *J Med Ethics* 2015; ■: 1–6.
- Kass NE, Sugarman J, Faden R, et al. Trust: the fragile foundation of contemporary biomedical research. *Hastings Center Rep* 1996; 26(5): 25–29.
- Caulfield T, Rachul C and Nelson E. Biobanking, consent, and control: a survey of Albertans on key research ethics issues. *Biopreserv Biobanking* 2012; 10: 433–438.
- Secko DM, Preto N, Niemeyer S, et al. Informed consent in biobank research: a deliberative approach to the debate. *Social Sci Med* 2009; 68: 781–789.
- Walmsley HL. Stock options, tax credits or employment contracts please! The value of deliberative public disagreement about human tissue donation. *Social Sci Med* 2011; 73: 209–216.
- Platt J and Kardia S. Public trust in health information sharing: implications for biobanking and electronic health record systems. *J Pers Med* 2015; 5: 3–21.
- Kelly SE, Spector TD, Cherkas LF, et al. Evaluating the consent preferences of UK research volunteers for genetic and clinical studies. *PLoS One* 2015; 10: e0118027.
- Corrigan O and Tutton R. What's in a name? Subjects, volunteers, participants and activists in clinical research. *Clin Ethics*. 2006; 1: 101–104.
- Watanabe M, Inoue Y, Chang CF, et al. For what am I participating? The need for communication after receiving consent from biobanking project participants: experience in Japan. *J Hum Genet* 2011; 56: 358–363.
- Whitley EA. Towards effective, consent based control of personal data. In: O'Hara K, Hildebrandt M and

- Waidner M (eds) *Digital enlightenment forum yearbook*. Amsterdam: IOS Press, 2013, pp. 165–176.
31. Kaye J, Curren L, Anderson N, et al. From patients to partners: participant-centric initiatives in biomedical research. *Nat Rev Genet* 2012; 13: 371–376.
 32. Kaye J, Whitley EA, Lund D, et al. Dynamic consent: a patient interface for twenty-first century research networks. *Eur J Hum Genet* 2015; 23: 141–146.
 33. Thiel DB, Platt J, Platt T, et al. Testing an online, dynamic consent portal for large population biobank research. *Public Health Genomics* 2014; 18: 26–39.
 34. Hoeyer K. Donors perceptions of consent to and feedback from biobank research: time to acknowledge diversity? *Public Health Genomics* 2010; 13: 345–352.
 35. Whitley EA, Kanellopoulou N and Kaye J. Consent and research governance in biobanks: evidence from focus groups with medical researchers. *Public Health Genomics* 2012; 15: 232–242.
 36. Gibbs A. Focus groups. *Social Res Update* 1997; 19(8): 1–8.
 37. Kitzinger J. Introducing focus groups. *Br Med J* 1995; 311: 299–302.
 38. Fern EF. The use of focus groups for idea generation: the effects of group size, acquaintanceship, and moderator on response quantity and quality. *J Marketing Res* 1982; 19: 1–13.
 39. Krueger RA. *Focus groups: a practical guide for applied research*. London: Sage, 1988.
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